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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,550	01/26/2001	Komei Washino	Q62780	9592

7590

05/06/2004

Sughrue Mion Zinn
Macpeak & Seas
2100 Pennsylvania Avenue NW
Washington, DC 20037-3202

EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,550

Applicant(s)

WASHINO ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-34 and 36-43 is/are pending in the application.
- 4a) Of the above claim(s) 22-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 36-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 22-34, 36-43 are pending. Claims 22-34 are withdrawn from consideration, as they are directed to non-elected subject matter. The Amendment filed 12/29/03, cancelled claim 35 and amended claims 36-37, 39-42.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-39, 41-43 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "the administrative form of the medicament" in claim 36 and 41, last line, lacks support in the original disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-39, 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 36 and 41 are vague and indefinite, as they are confusing. What is a concentration of the active ingredient equal to a concentration of the active ingredient in the administrative form of the medicament?

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al.

(Effects of 17O-Labeled Water. . .FKBP/Ascomycin Complex, Jn. Of Magnetic Resonance).

Yu teaches the effects of 17 O-labeled water on the backbone amide 1H relaxation rates of the FK506 binding protein (FKBP) and ascomycin. Thus, disclosed is a composition comprising FK506 binding protein, ascomycin and H217O (solvent and drug delivery system). See pg. 218.

It is respectfully pointed out that the effects of (H2)17-O on the proton bonded thereto are an inherent property of the compound, as a compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43.

It is further respectfully pointed out that since the binding protein/ascomycin complex is the only medicament, that the concentration of the active ingredient in the drug composition is equal to the concentration of the active ingredient in the medicament. The binding protein/ascomycin complex is the administrative form.

Regarding Applicant's limitations toward the relaxation effect spreading through the exchange of a proton in a vital component of a target organ or tissue of a living body, it is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

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distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the composition of the prior art is able to perform the intended use. Thus, Applicant's limitations toward the intended use are not given patentable weight.

Allowable Subject Matter

Claims 40-43 contain allowable subject matter, as the prior art neither teaches nor suggests a pharmaceutically acceptable composition comprising a compound comprising –33SH.

Response to Arguments

Applicant argues, “Yu et al. are quite silent as to the fact that a drug to be contained in the composition may be detected by nuclear magnetic resonance”. This argument is not persuasive, as it is not commensurate in scope with the instant claims. The instant claims are directed to a composition and not toward a method of detection by NMR.

Applicant argues, “the concentration of the active ingredient is fundamentally different between the composition of Yu et al. and the drug composition of the present application. In this respect, applicants point out that the object of the present application is quite different from that of Yu et al.”. This argument is not persuasive. First, it is respectfully pointed out that the object of the invention is irrelevant. Yu et al. and the instant claims teach the same composition. Second, Applicant argues that the concentrations are fundamentally different, but fails to explain or provide evidence as to a difference. As pointed out in the above rejection, since the binding protein/ascomycin complex is the only medicament, the concentration of the active ingredient in the drug composition is equal to the concentration of the active ingredient in the administrative

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form of the medicament. The binding protein/ascomycin complex is the administrative form.

Applicant argues that “the effect of the present invention cannot be obtained by the composition disclosed by Yu et al. . .the aqueous solution of the FKBP/ascomycine complex disclosed in Yu et al. is clearly different in the form as well as the concentration of the active ingredient from the present drug composition”. This argument is not persuasive. For the reasons stated above and in the above rejection, the compositions of Yu et al and the instant invention are the same. Arguments of different utilities are not persuasive, since the claims are directed toward compositions. Applicant’s argument that the compositions of Yu et al. are of different form is not commensurate in scope with the instant claims, which do not require the composition to be in a special form.

Applicant argues, “the drug compositions of the present application affects T2 relaxation time of the proton (H) by the 17O (claim 36) or 33S (claims 40 and 41) in the drug composition, at the time of the administration of the drug to a living body”. This argument is not persuasive. Again, Applicant is arguing differences in methods of use, when the claims are directed to compositions.

For reasons of record, the Declaration filed 4/17/03, is not persuasive to show unexpected results. The Declaration filed 4/17/03 merely provided data, data that was not even commensurate in scope with the instant claims. The declaration provided no comparative data between the instant claims and the closest prior art. The data was not clear and convincing and did not show statistical and practical significance.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this

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Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).


Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER